

VERIFICATION OF TRANSLATION

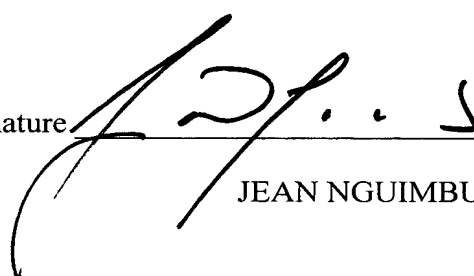
I, JEAN NGUIMBUS

of 1950 Roland Clarke Place
Reston, Virginia 20191

declare that I am well acquainted with both the French and English languages, and that the attached is a literal translation, to the best of my knowledge and ability, of the International Application No. PCT/FR03/00479, filed February 14, 2003.

I further declare that all statements made herein of my knowledge are true and that all statements made on information and belief are believed to be true; and, further, that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the above-captioned application or any trademark issued thereon.

Signature

A handwritten signature in black ink, appearing to be 'J. Nguimbus', written over a horizontal line.

JEAN NGUIMBUS

Date

December 21, 2004

METHOD AND DEVICE FOR MEASURING AND CONTROLLING THE CIRCULATION OF FLUIDS IN ENDOSCOPE CHANNELS

[0001] The invention relates to a method and a device for measuring and controlling the circulation of fluids in endoscope channels, having the object of verifying and recording the flow of cleaning, disinfecting, rinsing, and drying solutions passing through each of the endoscope channels during operations adapted to clean and disinfect them.

[0002] Endoscopes 1 (Figure 1) are apparatuses used in hospitals. They comprises a control box 2 at one of the ends of an exploration tube 3 adapted to be inserted through a natural conduit into an inner cavity of a patient's body in order to perform the diagnosis of lesions or certain treatments such as, for example, extracting foreign bodies, destroying tumors by coagulation or resection, introducing medicines or substances that are impervious to x-rays. The exploration head is connected by a second tube 4 to a proximal portion 5 comprising a series of injection couplings 6.

[0003] These are complex apparatuses comprising in a same tube optic fibers guiding the light coming from a generator, optic fibers carrying images or a video sensor (CCD), as well as various channels, such as operating channels, suction channel, air insufflation channel, water insufflation channel, erecting channel, washing channel. To make the endoscope compact, some of them can be joined in their downstream portion so as to form a single channel. For example, this may be the case for the air and water channels which form a common channel over the last centimeters of the insertion tube of the endoscope, and for the operating channels that join the suction channel. The flows circulating in the endoscope can also be mixed in a chamber (piston cage) having the same number of inlets and outlets.

[0004] The real difficulty in cleaning and disinfecting these apparatuses relates to these inner channels in which the circulation of the fluids can be non-existent or inefficient due to their diameter (0.5 – 4 millimeters). Insufficient pressure does not allow the passage of the solutions, and too much pressure can

damage the channels. Furthermore, in view of the interrelation of the channels, it is difficult for the operator to ensure that the circulation of the fluids was sufficient in each channel portion. It is then impossible to ensure that the washing and disinfecting processes were efficient.

[0005] To ensure that the various commercially available cleaning and disinfecting processes are efficient, whether they are manual or automated, it is necessary to perform samplings in each of the portions of the channels. To this end, a trained technician (generally a hygienist or a pharmacist) circulates sampling solutions by means of a syringe. These solutions are capable of detaching germs that may remain on the walls of the endoscope channels, and of neutralizing possible disinfectant residues that could vitiate the sampling results.

[0006] This handling is constraining as it requires irrigating each of the inlets of the various endoscope channels, one after the other, with all of the possible risks of contamination associated with the handling. It also requires rinsing and disinfecting the endoscope again.

[0007] Due to the cumbersomeness of this handling and of the protocol associated therewith, and the need to use trained technicians, who often are in a limited number in the hospital, these samplings are rarely performed.

[0008] An automated system for cleaning and disinfecting flexible endoscopes has been previously described in the French Patent No. 2 705 896. It makes it possible to circulate the fluids in the outer portions of the endoscope, as well as independently in each of the inner channels of the endoscope. However, this system does not make it possible to automatically ensure that the cleaning/disinfecting/rinsing/drying fluids have indeed circulated in each portion of each channel. If the endoscope is incorrectly coupled to the automaton, or if the one or several channels are partially or completely closed, the flow and concentration of the cleaning/disinfecting/rinsing/drying solutions through the endoscope, as well as the dwell time can be substantially reduced or even eliminated, resulting in an incomplete disinfection of the instrument.

[0009] With respect to safety for the patient, this is currently the most significant flaw in machines of this type. That is the reason why the operators are required to first ensure that none of the channels is closed, and to verify at the end of the cycle that the channels are properly coupled.

[0010] Nonetheless, certain automatons have been equipped with flow meters or pressure sensors in order to control the flow or the pressure in each of the channels. All of these methods attempt to determine the volume circulating in the channels in a time unit. The volume is deducted from the interpretation of a measuring sensor (pressure drop, number of impulses of a wheel).

[0011] However, these solutions encounter a number of problems:

- They are expensive, as they require as many sensors as channel portions to be controlled (up to 8 depending on the endoscopes).
- In order to allow for an accurate control, the flow or pressure delivered at the inlet of the channels cannot be optimized. As a result, the control times are long, up to several minutes per channel controlled, which can increase the total time of the cycles.
- They do not guarantee that a minimum volume corresponding to the saturation of the channel controlled has indeed circulated in the channel.
- The diagnosis of a proper circulation in the channel only relies on the indications provided by a single sensor. The failure of this sensor can cause a serious diagnosis error.
- Finally, they require frequent calibrations, and in view of the diverse types of channels, from one mark to the next, the adjustments of the thresholds turn out to be compromises. These adjustments set off false alarms that lead the users to frequently deactivate these safety mechanisms.

[0012] The device, which is the object of the present invention, makes it possible to ensure, by means of a limited number of devices not relying on the sensor interpretation, that the fluids circulate in each of the inner channels of the endoscope, with a flow that is well characterized and recorded during each of the endoscope cleaning, disinfecting, rinsing, and drying phases.

[0013] Due to a system that allows increasing the pressure of the flow passing through the endoscope channels and ensuring that a known solution volume has indeed circulated in said channels, and allows verifying and recording the flow in each channel at a given pressure, the invention makes it possible to ensure that each of them has indeed been cleaned, disinfected, rinsed, and dried by guaranteeing the presence of an adequate volume of the solution involved to saturate the channel for a predetermined period of time. It also makes it possible to use the optimum pressure and flow for each of the channels so as to ensure the optimum mechanical effect in the shortest time possible. Finally, its object is to provide the user with a quick and reliable means for sampling all of the portions of the endoscope inner channels, at the end of the cycle, in order to be able to analyze its possible state of contamination.

[0014] The device is constituted of a hermetic chamber having a known volume and provided with a low level and high level sensor allowing to control and record the filling and emptying thereof, and the upper portion of which is coupled to a filtered air compressor controlled by a pressure sensor, to a connection solenoid valve that allows air to evacuate while said chamber is being filled, to an injection pump that allows injecting a product promoting the drying, and to a circulation pump circulating the cleaning and disinfecting products contained in a tank that can receive at least one endoscope, this tank comprising injectors to which the endoscope channels can all be individually connected, said injectors being each coupled to the lower part of the hermetic chamber by means of a connecting pipe, an injection solenoid valve being arranged between the hermetic chamber and the injector on each of these connecting pipes.

[0015] An example of embodiment is provided below, the general scope of which is not limited in any way by the particularities or to the particularities of the example selected for illustrative purposes.

[0016] In the attached drawing:

- Figure 1, previously mentioned, shows an endoscope of the common type, and
- Figure 2 is the synoptic diagram of a device according to the invention.

[0017] As in the patent cited hereinabove, the control device, object of the present invention, is composed of a tank 10 and comprises a cap 11 equipped with an inflatable joint connected to a source of compressed air for ensuring that the assembly is impermeable once the cap is closed.

[0018] In particular, it comprises a circulation pump P1 that agitates the solutions in the tank 10 in which the endoscope 1 is positioned. Through two nonreturn valves C1, C2, this pump feeds a hermetic chamber 12 having a known volume that is preferably equal to at least one time the maximum volume of the largest channel of one endoscope.

[0019] The tank 10 is filled by means of solenoid valves V1, V4 connected to a rinsing water network. This water is filtered at 0.2 microns. The solenoid valves are connected to the hydraulic circuit coming from the circulation pump, between the valves C1 and C2.

[0020] A heating body allows heating the solutions prior to reinjecting them in the tank by means of two types of injectors 13, 13' making it possible, for some, to circulate the solutions around the outer portion of the endoscope 1, and for the others, to individually irrigate the inner channels of the apparatus.

[0021] The bottom of the tank is coupled to a drain pump that makes it possible to reject the solutions in the waste water network.

[0022] The unused injectors are coupled to tubes having an inner cross-section that is less than 5 mm, with a free end.

[0023] The top of the hermetic chamber 12 is coupled to a connection solenoid valve V2, the downstream portion is coupled to the tank 10, or to the cap 11 thereof, by means of quick connector 14 that can be easily accessed by the user from the outside of the machine, and which makes it possible to quickly and easily inject in the chamber, by means of a syringe or a pump, a solution, for example, a sampling solution, that can be collected after opening

one or several solenoid valves at the end of one or several channels of the endoscope 1. The bottom of the chamber is coupled to the injection solenoid valves V3 which each are coupled to a special injector connector 13 in the tank, this connector being itself coupled to one of the inlets of the channels of the endoscope 1. A pump P2 for injecting a drying fluid (e.g., alcohol) is coupled by means of a nonreturn valve C5 to the line coming from the air compressor, between the valves C3 and C4.

[0024] The connection solenoid valve (V2) is coupled to the tank (10), or to the cap (11) of the tank, such that air and the solutions for filling the hermetic chamber (12) can return to the tank, either above or below the level of the fluid contained in said tank.

[0025] The hermetic chamber 12 is also equipped with a low level sensor N1 and a high level sensor N2.

[0026] A plurality of hermetic chambers having different volumes can be used together to control the flow of a plurality of endoscopes, or to more quickly control the flow in sets of channels of the same endoscope having similar diameters.

[0027] The system is equipped with a filtered air compressor 15 that feeds the hermetic chamber 12 at a given pressure through a line comprising a calibrated valve or two nonreturn valves C3, C4 between which a shunt pressure sensor 16 is inserted, and which makes it possible to control the pressure delivered in the chamber at different set values.

[0028] The cleaning and disinfecting products are injected in concentrated form in the tank 10 by means of an apportioning device. Next, they are diluted therein through agitation by means of the circulation pump P1. The standard cycle generally includes the following sequences:

- Filling the tank
- Injecting the cleaning product
- Activating the circulation pump, cleaning the outer sheath of the endoscope and irrigating the endoscope channels
- Draining the tank

- Rinsing the tank and the endoscope channels with filtered water
- Filing the tank
- Injecting the disinfecting product
- Activating the circulation pump, disinfecting the outer sheath of the endoscope and the endoscope channels
- Draining the tank
- Rinsing the tank and the endoscope channels with filtered water
- Drying the channels

[0029] All of the electromechanical components are guided by an automaton having a microprocessor which, depending on the state of the sensors (level, pressure, temperature), manages the cycle as well as an interruption alarm assembly.

[0030] The endoscopes 1 that are treated in this device comprise a label or a chip that makes it possible to feed the automaton by means of a reader with information about the mark of the endoscope, its serial number, as well as its type. The automaton has been programmed beforehand with data from the manufacturers of the endoscope regarding the length and diameter of the channels of which it is constituted.

[0031] For the connection to the inlets of the endoscope 1, separators are positioned beforehand in the piston cage 7 (Figure 1) common to the air and water channels so as to separate the flows. These separators are machined so as to maintain a tiny communication between the two circuits that enables the disinfectant to act and not create any dead zone that cannot be disinfected. The communication should not permit a leakage greater than 30% of the flow in each of them.

[0032] For some of the endoscope channels, particularly those having an inner diameter greater than 3 mm, the coupling for connecting to the endoscope is equipped with a closing device that allows circulation only if the coupling is properly connected to the channel inlet.

[0033] Each of the inlets of the endoscope is coupled to a distinct injector 13 located in the tank 10 and capable of being identified for the

coupling of at least one of the following channels: biopsy channel, suction channel, auxiliary biopsy channel or water jet channel, air channel, water channel, erecting channel, and auxiliary water channel.

[0034] Below is described the principle of controlling the irrigation of one of the channels with the solutions coming from the tank by means of the device according to the invention. This control is carried out in the following steps:

[0035] 1. The state of the level sensors N1, N2 of the hermetic chamber 12 is verified. If the chamber is not empty, the air compressor 15 is activated at the same time as the channel solenoid valve V3 so as to empty the chamber.

[0036] 2. As soon as the level sensors provide the adequate indication, the compressor 15 is activated until a set value (Pa) recorded in the automaton is reached by the pressure sensor 16.

[0037] 3. A waiting time (TT) recorded in the automaton is observed. If, at the end of this time, the pressure in the chamber is still greater than (Pa-x), the control sequence is continued. Otherwise, an alarm indicates that there is a leakage in the circuit, and that the test cannot be properly conducted.

[0038] This operation makes it possible to ascertain that the hermetic chamber 12 and all of the channel solenoid valves V3 coupled thereto are impermeable prior to any filling.

[0039] The values (TT), (Pa), and (x) are determined as a function of the cross-sections and volumes of the circuits and of the hermetic chamber 12, so that the diagnosis time is optimized.

[0040] 4. The connection solenoid valve V2 is open and the circulation pump P1 is activated so as to fill the hermetic chamber 12 with the solution coming from the tank 10. The time (T1) for reaching the high level (sensor N2) is timed and recorded in the automaton.

[0041] 5. As soon as the high level sensor N2 indicates that the chamber is full, the action is maintained for a waiting time equal to half the filling time (T1/2) so as to ensure that the circuit is saturated up to the connection solenoid valve V2.

- [0042]** 6. Simultaneously:
- the circulation pump P1 is deactivated
 - the connection solenoid valve V2 is closed
 - the solenoid valve V3 coupled to the channel to be controlled is opened
 - the air compressor 15 is activated as long as the pressure indicated by the pressure sensor 16 does not exceed the maximum pressure (PM) authorized for the irrigation of the channel connected to the open channel solenoid valve V3.
 - a timing is performed until the low level sensor N1 indicates that the chamber 12 is empty.

[0043] The value of the pressure (PM) to be applied in the chamber must make it possible to inject the confined solution volume in the chamber in the shortest time without however damaging the endoscope channels. It is comprised between 400 and 3,500 mbars depending on the channels.

[0044] 7. Knowing the volume and the time makes it possible to determine the flow, to record it in a memory of the microprocessor and to compare it to a reference flow of an endoscope of the same type of this same channel, which had been previously recorded in the automaton at the factory (when the endoscope is known), or during the installation of the machine (if the endoscope is a less widely used model). The reference time obtained can advantageously be recorded in the automaton or in an external database connected to the automaton.

[0045] If the time is greater than the reference value increased by a coefficient (KB), it can be concluded that the channel is closed.

[0046] If the time is less than the reference value decreased by a coefficient (KD), one can conclude that the channel is disconnected, or that there is a leakage between the outlet of the solenoid valve V3 and the inlet of the endoscope channel.

[0047] In the case where the flows are within the prerecorded acceptable limit of the values, they are printed at the end of the cycle on the cycle validation card or transferred to a storage medium. Otherwise, the cycle is interrupted and a message indicates the cause as well as the channel from which the flaw originated.

[0048] 8. If the endoscope 1 is provided with a bundle of channels having a common portion (e.g., biopsy and suction channel), the above sequence is repeated but by opening at step 5 all of the solenoid valves coupled to the channels having common portions with the channel to be treated, for example, the biopsy channel and suction channel.

[0049] 9. Knowing the volume and the time makes it possible to determine the flow, to record it in a memory of the microprocessor and to compare it to a reference flow that is characteristic of the emptying of the hermetic chamber 12, simultaneously through all of the channels of the same chamber.

[0050] In the case where the flows are within the prerecorded acceptable limit of the values, they are printed at the end of the cycle on the cycle validation card or transferred to a storage medium. Otherwise, the cycle is interrupted, and a message indicates the cause as well as the channel from which the flaw originated.

[0051] If the time is less than the reference value decreased by a coefficient (KDG), it can be concluded that one of the channels in the bundle is disconnected, or that there is a leakage between the outlet of the solenoid valve V3 and the inlet of the endoscope channel.

[0052] 10. At the end of the cleaning and disinfecting phases and during the emptying of the tank 10, the connection solenoid valve V2 and the solenoid valve V1 for filling the filtered water are opened for the time that is necessary for rinsing the chamber 12.

[0053] 11. Next, the solenoid valves V1, V2 are closed and the compressor 15 is activated at the same time as the channel solenoid valves V3

are opened, until the level sensor N1 indicates that the chamber 12 is empty. The channels have thus been rinsed with clean water.

[0054] 12. The compressor 15 is activated and the channel solenoid valves V3 are opened for the time that is necessary for draining the endoscope 1.

[0055] This flow control sequence in the channels is activated one or several times for all of the channels during each phase of the cycle, with the solution being present in the tank 10, namely:

- when filling the tank with water
- when cleaning
- when rinsing after cleaning
- when filling the tank 10 the second time
- when disinfecting
- when rinsing after disinfecting
- when filling the tank 10 the third time
- when rinsing

[0056] During the periods where the control is not activated, all of the channel solenoid valves V3 are opened such that the flow coming from the filling solenoid valve V1 (irrigation with filtered water) or from the circulation pump P1 (irrigation with a cleaning or disinfecting solution) passes freely in the tank 10 to irrigate all of the channels.

[0057] The device also makes it possible to check a volume of drying fluid (e.g., alcohol) injected in the channels. To this end, the connection solenoid valve V2 and the drying fluid pump P2 are activated until the high level (sensor N2) of the chamber 12 is reached.

[0058] Next, the channel solenoid valves V3 and the air compressor 15 are opened until the low level sensor N1 indicates that the tank 10 is empty; then, for the time necessary for draining or evaporating the drying fluid.

[0059] At the end of the cycle, the cap 11 is opened, and samplings can be undertaken without it being necessary to disconnect the endoscope 1.

[0060] To this end, the quick coupling 14 is disconnected and the portion coming from the hermetic chamber 12 is coupled to the downstream portion of the body of a peristaltic pump. This body (silicone pipe) will have previously been sterilized. The upstream portion of the body of the pump is coupled to a sampling fluid flask. The distal end of the exploration tube 3 of the endoscope is inserted in a sterile sampling jar.

[0061] The operator can then select the channel to be sampled by means of touch keys on the data entry screen of the automaton. As long as the touch key is activated, the peristaltic pump and the solenoid valve V3 corresponding to the selected channel are activated. The sampling fluid pushed by the peristaltic pump comes back out through the end of the channel and is collected in the jar. Once the adequate quantity has been collected, the touch key is deactivated, and the sampling of the next channel can be undertaken.

[0062] A sequence can also be programmed to automatically sample one channel after the other.

[0063] The end of the endoscope is then removed from the collection jar, the quick coupling 14 connected to the machine, and a cycle is relaunched so as to rinse and disinfect the endoscope again.

[0064] The particularities appearing in the preceding description provide the object of the invention with a maximum of useful effects that, until now, had not been obtained by similar devices or methods.